REMARKS

Claims 1-3, 6, 9, 13, 36, 43-50 were pending. Applicants have amended claim 6 to clarify the claimed subject matter. This amendment does not introduce any new matter. Entry of this amendment is requested such that claims 1-3, 6, 9, 13, 36, and 43-50 will be pending.

Rejections under 35 U.S.C. §112, Second Paragraph, Indefiniteness

Claim 6 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. The Examiner alleges that the phrase "morphogen activating element" lacks proper antecedent basis, and suggests replacing the term "morphogen" with "transcription." Applicants have amended claim 6 in accordance with the Examiner's suggestion, thereby obviating this ground of rejection.

Rejections under 35 U.S.C. §112, First Paragraph, Written Description

Claims 1-3, 6, 9, 13, 36, 43-50 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges that the genus of "transcription activating elements" (TAEs) is not sufficiently described in the specification.

The Examiner invites Applicants to overcome this ground of rejection by identifying "several other known prior art transcriptional activating elements which would function in the same way as the mouse type X collagen promoter in the claimed assay." (page 2, first paragraph of the Office Action).

In response, without conceding the correctness of this ground of rejection, Applicants provide in Table 1 below a representative number of genes whose transcription was responsive to a morphogen, and therefore contain transcription activating elements responsive to a morphogen, including N-CAM, Osteocalcin, L1, Alkaline Phosphatase, Collagen Type II, Collagen Type IV and Id (Inhibitor of Differentiation).

Table 1

Gene	Cell/ Species	Morphogen	Disclosure	Reference/Pub Date
Osteocalcin	MLB13MYC Mouse Prechondroblastic Cells	BMP-2	Paragraphs 1-3	Goto et al. (1994) J. Bone Miner Res 9 (suppl.1):s254) **(Exhibit A)**
N-CAM	NG108-15 Mouse Neuroblastoma x Rat Glioma Hybrid Cells	OP-1, BMP-2, BMP-4, BMP-5 and BMP-6	(Fig 3B)	Perides et al. J Biol Chem. 1994 Jan 7;269(1):765-70 **(Exhibit B)**
N-CAM	NG108-15 Mouse Neuroblastoma x Rat Glioma Hybrid Cells	OP-1, BMP-2, BMP-4, BMP-5 and BMP-6	(Fig 3B)	Perides et al. J Biol Chem. 1994 Jan 7;269(1):765-70 **(Exhibit B)**
L1	NG108-15 Mouse Neuroblastoma x Rat Glioma Hybrid Cells	OP-1, BMP-2, BMP-4, BMP-5 and BMP-6	(Fig 3C, bottom panels)	Perides et al. J Biol Chem. 1994 Jan 7;269(1):765-70 **(Exhibit B)**
Type II Collagen	Rat Calvarial Cells	OP-1	(Fig 3)	Asahina et al. J Cell Biol. 1993 Nov;123(4):921-33. **(Exhibit C)**
Type IX Collagen	Rat Calvarial Cells	OP-1	(Fig 3)	Asahina et al. J Cell Biol. 1993 Nov;123(4):921-33. **(Exhibit C)**
Osteocalcin	Rat Calvarial Cells	OP-1	(Fig 5B)	Asahina et al. J Cell Biol. 1993 Nov;123(4):921-33. **(Exhibit C)**
Alkaline Phosphatase	Rat ROB-C26 Cells	BMP-2	(Fig 3)	Yamaguchi J Cell Biol. 1991 May;113(3):681-7. **(Exhibit D)**
Osteocalcin	Rat ROB-C26 Cells	BMP-2	(Fig 4B)	Yamaguchi J Cell Biol. 1991 May;113(3):681-7. **(Exhibit D)**
Osteocalcin	Mouse W-20-17 Stromal Cells	BMP-2	(Fig 7, bottom panel)	Thies et al. Endocrinology. 1992 Mar;130(3):1318-24.

				(Exhibit E)
Id (Inhibitor of Differentiation)	Mouse MC3T3-E1 Cells Rat C3H10T1/2 Cells Rat Calvarial Cells	BMP-2	(Fig 1 A, B) (Fig 4) (Fig 5)	Ogata et al. Proc Natl Acad Sci U S A. 1993 Oct 1;90(19):9219-22. **(Exhibit F)**
Type I Collagen	Rat Osteosarcoma Cells	OP-1	(Fig 2B)	Maliakal et al. Growth Factors. 1994;11(3): 227-34. **(Exhibit G)**
Alkaline Phosphatase	Rat Osteosarcoma Cells	OP-1	(Fig 3B)	Maliakal et al. Growth Factors. 1994;11(3): 227-34. **(Exhibit G)**
Osteocalcin	Rat Osteosarcoma Cells	OP-1	(Fig 4B)	Maliakal et al. Growth Factors. 1994;11(3): 227-34. **(Exhibit G)**

The representative number of genes provided containing transcription activating elements responsive to a morphogen are sufficient to satisfy the written description requirement set forth by the federal Circuit in Lilly. See Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1569 (Fed. Cir. 1997) (Written description of a genus requires disclosure of a representative number of species falling within the genus).

Although the references cited above were not cited in the specification, what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d at 1384, 231 USPQ at 94. See also MPEP 2163(II)(A)(3)(a). All the references cited in Table 1 were publicly available at the time of the earliest claimed priority date of July 26, 1995.

Reconsideration and withdrawal of this ground of rejection is requested.

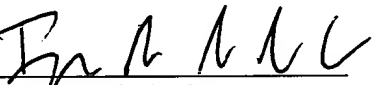
CONCLUSIONS

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Applicants believe no fee is due with this response in addition to those listed in the fee transmittal sheet. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. JJJ-P02-540 from which the undersigned is authorized to draw.

Dated: November 14, 2006

Respectfully submitted,

By 

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